

## **REMARKS**

With the cancellation of claim 15, claims 1-14 are pending. Claim 1 has been amended to add an additional limitation “wherein said copolyester comprises hydroxybutyric acid units.” Claim 3 has been amended to further define the species of the oil or fat to be used in the invention. These amendments are supported at least by the specification in page 5, line 29 to page 6, line 11; page 9, line 27 to page 10, line 1. Claims 5, 6, and 8 have been amended to correct clerical errors. Applicants respectfully submit that no new matter has been introduced.

### **Objections to claims 5 and 8**

Claims 5 and 8 were objected to because of informalities. Claims 5 and 8 have been amended as suggested by the Examiner. The phrase “under the condition phosphorus being restricted” has been replaced with “under conditions where phosphorus is restricted.” “Unit” at the end of claim 8 has been changed to “units.” Applicants respectfully request withdrawal of the objections to claims 5 and 8.

### **Claim Rejections under 35 U.S.C. 112, Second Paragraph**

Applicants respectfully traverse the rejections of claims 3 and 15 as being indefinite under 35 U.S.C. § 112, second paragraph. Claim 15 has been cancelled, rendering the rejection moot.

Without conceding to the propriety of the rejection and in order to expedite prosecution, claim 3 has been amended to recite “controlling a composition of the produced copolyester by selecting a species of oil or fat... wherein the oil or fat contains at least one oil or fat selected from the group consisting of soybean oil, corn oil, cottonseed oil, palm oil, palm kernel oil, coconut oil, peanut oil, and fractionated oils obtained by fractionating these oils.” Applicants respectfully submit that amended claim 3 is in compliance with the definiteness requirement of 35 U.S.C. § 112, second paragraph. Withdrawal

of the rejection of claim 3 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

### **Claim Rejections under 35 U.S.C. 112, First Paragraph**

Applicants respectfully traverse the rejections of claims 1, 3-8 and 15 as allegedly failing to comply with the written description and enablement requirements under 35 U.S.C. § 112, first paragraph. Claim 15 has been cancelled, rendering the rejection of claim 15 moot.

The Office Action states that the genus recited in claim 1 is broad while the application discloses a single representative species, i.e. p (HB co HH). Office Action, page 4, the last line to page 5, line 6. Without conceding to the propriety of the rejection and in order to expedite prosecution, claim 1 has been amended to recite a method of producing copolyester “wherein said copolyester comprises hydroxybutyric acid units.” The specification describes, in an enabling way, a method of producing poly(3HB-co-3HH) comprising controlling a specific substrate feed rate of an oil or fat to be used as a carbon source at a constant value throughout the whole culture period (page 10, lines 26-31; page 23, Example 3, Table 4). The specification further provides enabling written description for a method of producing a copolyester having hydroxybutyric acid units, the method comprising controlling a composition of the produced copolyester by selecting a species of oil or fat and/or by controlling the specific substrate feed rate (Examples 1-4).

The Office Action rejects claim 3 for lack of written description and enablement on the grounds that the specification “fails to present any identifying characteristics of oils or fats which result in high levels of incorporation of the non-HB monomer of the PHA copolyester.” Office Action, page 5, lines 13-16; page 9, lines 2-5. Claim 3 has been amended to recite “wherein the oil or fat contains at least one oil or fat selected from the group consisting of soybean oil, corn oil, cottonseed oil, palm oil, palm kernel oil, coconut oil and peanut oil, and fractionated oils obtained by fractionating these oils.” The specification discloses that poly(3HB-co-3HH) with a relatively low 3HH content of 1 to 10

mol% may be obtained using corn oil, cottonseed oil, palm oil, palm kernel oil, coconut oil and peanut oil, and fractionated oils of these oils (page 9, lines 30-32). In addition, Example 4 demonstrates the dependence of the 3HH content (mol%) on the ratio of palm kernel olein oil to soybean oil in mixed oils. These written descriptions enable an ordinary skilled in the art to control the monomer composition of a copolyester comprising hydroxybutyric acid units by selecting a species of oil or fat from the group of the oils and fats recited in amended claim 3.

For at least the foregoing reasons, claims 1 and 3-8 are fully in compliance with the written description and enablement requirements under 35 U.S.C. §112, first paragraph. Withdrawal of the rejections is respectfully requested.

#### **Claim Rejections under 35 U.S.C. 103**

Applicants respectfully traverse the obviousness rejections of claims 1, 3-8, and 15 over Satoshi et al. (JP 2001/340078) in view of Naylor et al. (WO 96/25509). The cancellation of claim 15 renders its rejection moot.

Claim 1 recites a method of producing copolyester by a culture of a microorganism which comprises controlling a specific substrate feed rate of an oil or fat to be used as a carbon source at a constant value throughout the whole culture period. The specific substrate feed rate of an oil or fat is defined as an amount of an oil or fat supplied per net weight cells during a unit time. Specification, page 11, lines 3-9. In other words, the specific substrate feed rate of an oil or fat is a culture parameter defined as a feed rate of an oil or fat per net weight cells (page 19, lines 34-35). Applicants have found that the molar ratio of 3HH in the copolymer p(3HB-co-3HH) increases as the specific substrate feed rate decreases (page 14, lines 34-35).

As acknowledged in the Office Action, Satoshi does not teach “keeping a constant specific substrate feed rate (i.e., a constant value of fat or oil added per net weight of cells).” Office Action, page 11, lines 9-11. The Office Action

then states in page 11, lines 15-16 that Naylor teaches “maintaining a constant oil uptake rate (i.e., 0.13 g/g of non-PHA cell mass/hour (see page 7).”

Applicants respectfully disagree. Naylor discloses in page 7, lines 15-17 that “rape seed oil was fed to achieve an average oil **uptake rate of up to 0.13g** per g of non-PHA cell mass per hour.” This sentence refers to an average oil **uptake rate**, which is the consumption rate of rape seed oil by the cells. The average oil **uptake rate** is distinct from the specific substrate feed rate of the claimed invention, which is defined as the **supply rate** per net weight of dried cells, regardless of the actual consumption rate of oils or fats by the cells. Furthermore, Naylor merely discloses that the rape seed oil was fed to achieve an average oil uptake rate of **up to 0.13g** per g of non-PHA cell mass per hour (page 7, lines 15-17). Contrary to the statement in the Office Action (page 11, lines 15-16), Naylor does **NOT** teach or suggest that the average oil uptake rate be controlled at a **constant** value, as recited in the present claim 1. Indeed, Naylor disclosed that the rate of oil uptake decreased substantially after 20 hours (page 7, lines 18-19).

Applicants have found that by adjusting the specific substrate feed rate, one can control the 3HH molar ratio in the poly(3HB-co-3HH). Specification at page 14, line 33 to page 15, line 12. By contrast, Naylor fails to recognize any effect of the oil uptake rate on the monomer composition of the copolyester at all. With regard to controlling the monomer composition of the copolyester, Naylor merely discloses in page 4 that “If the aliphatic acid contains an even number of carbon atoms and is the sole carbon source in step (e) the product PHA is substantially or wholly polyhydroxybutyrate (PHB) homopolymer. If polyhydroxybutyrate/valerate copolymer (PHBV) is required, there should be present a carbon source containing an odd number of carbon atoms.”

In addition, it is difficult to measure the oil uptake rate of Naylor. Compared to the oil uptake rate, the specific substrate feed rate of the claimed invention can be controlled much more easily.

In summary, the present invention would not have been obvious over Satoshi in view of Naylor. Withdrawal of the obviousness rejections of claims 1 and 3-8 is respectfully requested.

## **CONCLUSION**

The Examiner is encouraged to contact the undersigned regarding any questions concerning this amendment. In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The Commissioner is authorized to debit Deposit Account No. 11-0600 the petition fee and any other fees that may be required in relation to this paper.

Respectfully submitted,  
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